

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (Amendment)

4 900 KAR 5:020. State Health Plan for facilities and services.

5 RELATES TO: KRS 216B.010-216B.130

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28)
7 [216B.015(27)], 216B.040(2)(a)2a

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)2.a requires
9 the cabinet to promulgate an administrative regulation, updated annually, to establish
10 the State Health Plan. The State Health Plan is a critical element of the certificate of
11 need process for which the cabinet is given responsibility in KRS Chapter 216B. This
12 administrative regulation establishes the State Health Plan for facilities and services.

13 Section 1. The 2012 [2014] Update to the 2010-2012 State Health Plan shall be
14 used to:

15 (1) Review a certificate of need application pursuant to KRS 216B.040; and

16 (2) Determine whether a substantial change to a health service has occurred
17 pursuant to KRS 216B.015(28)(a) and 216B.061(1)(d).

18 Section 2. Incorporation by Reference. (1) The "2012 [2014] Update to the 2010-
19 2012 State Health Plan", November 2012 [May 2014], is incorporated by reference.

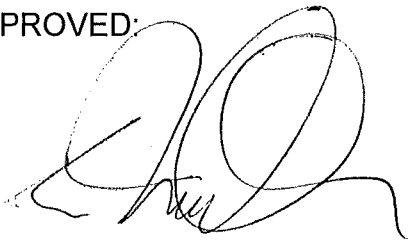
20 (2) This material may be inspected, copied, or obtained, subject to applicable
21 copyright law, at the Office of Health Policy, 275 East Main Street, fourth floor,

1 Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

900 KAR 5:020

This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

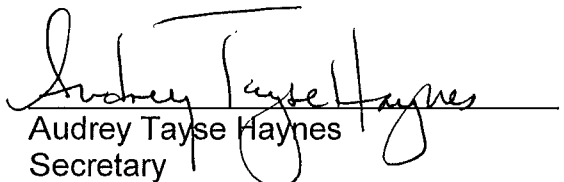
APPROVED:



Eric Friedlander
Acting Executive Director
Office of Health Policy

11/14/12
Date

APPROVED:



Audrey Tayse Haynes
Secretary
Cabinet for Health and Family Services

11/14/2012
Date

900 KAR 5:020

PUBLIC HEARING AND COMMENTS:

A public hearing on this administrative regulation shall, if requested, be held on December 21, 2012, at 9:00 a.m. in the Public Health Auditorium located on the First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business January 2, 2013. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, (502) 564-7905, Fax: (502) 564-7573

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation Number: 900 KAR 6:020

Contact Person: Eric Friedlander or Chandra Venettozzi, (502) 564-9589

1. Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation incorporates by reference the 2012 Update to the 2010 – 2012 State Health Plan, revised November, 2012. The 2012 Update to the 2010 – 2012 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a.
- (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), 216B.040(2)(a)2a.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of 216B.010-216B.130 by incorporating by reference the 2012 Update to the 2010 – 2012 State Health Plan, revised November, 2012. The 2012 Update to the 2010 – 2012 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a. KRS 216B.015(28) states the State Health Plan be prepared triennially and updated annually. This regulation incorporates the 2012 update to the State Health Plan.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 216B.040(2)(a)2.a by incorporating by reference the 2012 Update to the 2010-2012 State Health Plan.

2. If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: This amendment incorporates by reference the 2012 Update to the 2010-2012 State Health Plan.
- (b) The necessity of the amendment to this administrative regulation: This amendment is necessary as KRS 216B.015(28) states the State Health Plan be prepared triennially and updated annually.

This regulation incorporates the 2012 update to the State Health Plan.

- (c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by providing the 2012 update to the 2010-2012 State Health Plan.
 - (d) How the amendment will assist in the effective administration of the statutes: This amendment will provide the 2012 update to the 2010-2012 State Health Plan.
- 3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects entities wishing to file an application for a Certificate of Need. Approximately 160 entities file an application for a Certificate of Need each year.
- 4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Entities wishing to submit an application for a Certificate of Need will be subject to the revised criteria set forth in the revised 2012 update to the 2010-2012 State Health Plan.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No cost will be incurred by regulated entities to comply with this regulation.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities will now have revised criteria set forth in the revised 2012 update to the 2010-2012 State Health Plan so that they make more accurately complete their application for a Certificate of Need.
- 5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: No cost
 - (b) On a continuing basis: No cost

6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be from Office of Health Policy's existing budget. No additional funding will be required.
7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.
8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.
9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 900 KAR 5:020

Contact Person: Eric Friedlander or Chandra Venettozzi

Phone number: 502-564-9592

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation affects the Office of Health Policy within the Cabinet for Health and Family Services.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), 216B.040(2)(a)2a.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate any revenue in the subsequent years.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES

Office of Health Policy

900 KAR 5:020, State Health Plan for Facilities and Services

Summary of Changes to Material Incorporated by Reference

The 2012 Update to the 2010 – 2012 State Health Plan, revised November 2012 is being incorporated by reference. The 2012 Update to the 2010 – 2012 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a. The 2012 Update to the 2010 – 2012 State Health Plan includes revisions to the following:

- a. The introductory page was changed to reflect the change in dates within the title from the 2011 Update to the 2010 – 2012 State Health Plan (May, 2012) to 2012 Update to the 2010 – 2012 State Health Plan (November, 2012) and revision date of November 2012.
- b. The Table of Contents on page ii was revised to reflect changes in page numbers as a result of content change in the document.
- c. Page iii, item 3 was revised to correctly reference the form to be submitted for the addition or establishment of a health service or equipment.
- d. Page iv, item 5 was revised to clarify that facilities owned or operated by the Commonwealth are not included in need calculations.
- e. Page iv, item 8 was revised to include an additional phone number that may be used to reach the Office of Health Policy.
- f. Page iv, item 10 was revised to clarify that population estimates used will be obtained each May 1st rather than January 1st and to include an additional phone number that may be used to reach the Office of Health Policy.
- g. Page 5, item 2, Acute Care Beds was revised to clarify that only Licensed beds are counted in the target calculations.
- h. Page 7, item 3, Comprehensive Physical Rehabilitation Hospital Beds was revised to clarify that the formula is ADD specific rather than statewide and to clarify that plan year population is used in the formula.
- i. Page 9 – Special Care Neonatal Beds was revised to specify the new levels of neonatal care designated by the American College of Obstetrics and Gynecology *Guidelines for Perinatal Care* and where superseded by the more recent official

policy, the Policy Statement on Levels of Neonatal Care published by the American Academy of Pediatrics which is now included as attachment A. Also, language was added to address the need to have Level III beds available to the regions within Kentucky. Extensive new language was included to specify the need criteria for establishment of Level II, Level III, and Level IV special care neonatal beds.

- Level II must provide:
 - All services offered by Level I facilities.
 - Care only for infants ≥ 32 weeks gestation or who weigh ≥ 1500 grams at birth.
 - Ventilation limited to an interim basis.
 - Policies and procedures to ensure specified personnel are available.
 - Policies and procedures to ensure equipment are available.
 - Policies and procedures to ensure personnel are staffing units at all times.
 - Policies and procedures and transfer agreements to ensure referral to a higher level of care when needed.
- Level III need calculations were revised to include provisions that facilities recognized as a "high intensity level II neonatal center" pursuant to 907 KAR 10:825 may convert Level II beds to Level III and allow provisions for a facility to convert up to two additional Level II beds to Level III if the utilization of the existing Level III beds was 70% or greater in the last published utilization data.

Level III must provide:

- All services offered by Level II facilities.
 - Specified personnel that is continuously available.
 - Equipment to provide life support for as long as needed that is continuously available.
 - Advanced respiratory support and other support with pediatric expertise.
 - Ongoing assisted ventilation for periods longer than 24 hours.
 - Maternal-Fetal Medicine Specialists and pediatric medical subspecialists.
 - Readily available pediatric ophthalmology services.
 - Policies and procedures to ensure that complex surgical procedures are performed by pediatric surgical specialists.
 - Capability to perform advanced imaging with interpretation on an urgent basis.
 - Documentation of participation in the Vermont-Oxford Network and agree to submit outcomes data report to the Office of Health Policy annually.
 - Policies and procedures and transfer agreements to ensure referral to a higher level of care when needed.
- Level IV beds are a new category of beds that may be established by converting existing Level III beds to Level IV. Level IV must provide:
 - All services offered by Level III facilities.

- Documentation they can provide pediatric surgical services within the institution, including anesthesiologists with pediatric expertise, as well as pediatric surgical subspecialists.
- Policies and procedures to facilitate transport systems and provide outreach education in their catchment area.
- Documentation of the capability to collect data on long-term outcomes to evaluate the effectiveness of delivery of service and the safety and efficacy of new therapies.

With the addition of the above, the remaining pages were renumbered.

- j. Page 14, Mental Health Care, first paragraph was revised to add critical access hospitals in the definition of "psychiatric beds".
- k. Page 14, item 1 was revised to clarify that the adult and geriatric populations will be used when determining need for adult and generic beds as well as that child and adolescent populations will be used when determining need for child and adolescent beds.
- l. Page 14, item 2 was revised to clarify the need criteria for allocated adult psychiatric care beds.
- m. Page 14, item 3 was revised to clarify the criteria for additional adult beds and that each facility with licensed and allocated adult beds are considered in the need calculations.
- n. Page 15, new items 4 and 5 was added to provide specific need criteria for the child and adolescent population.
- o. Page 15, item 4 was renumbered to item 6 and subsection a. was revised to clarify an applicant must also meet the review criteria in Sections 1, 3 and 5 above.
- p. Page 15, item 5 was renumbered to item 7 and subsection a. was revised to clarify an applicant must also meet the review criteria in Sections 1, 3 and 5 above. Remaining sections were renumbered.
- q. Page 15, items 6 and 7 were renumbered to 8 and 9 respectively.
- r. Page 16, Psychiatric Services for Children and Adolescents, new item 1 was added to require the applicant for psychiatric services for children and adolescents to provide clear descriptions of which evidence-based practices will be utilized and how they will meet the clinical needs of the proposed population to be served. Remaining items were renumbered.
- s. Page 17, new item 4.f was added to require documentation of policies and procedures to ensure a case manager will be identified and appointment

schedules as part of the discharge planning process and in the case of a child, the case manager shall be involved in the discharge planning process.

- t. Page 20, item 9, Level I PRTF was revised to clarify the criteria applies to the primary services area.
- u. Page 20, item 9d was revised to clarify that written agreements are only required for local school districts located within the same county as the PRTF is located.
- v. Page 20, item 3, Level II PRTF was revised to clarify the number of Level II PRTF beds cannot exceed fifty (50) in a facility.
- w. Page 22, item 13 was revised to clarify the criteria applies to the primary services area.
- x. Page 20, item 13d was revised to clarify that written agreements are only required for local school districts located within the same county as the PRTF is located.
- y. Page 20, item 14 was revised to correctly spell PRTF.
- z. Page 25, Home Health Service was revised to allow for the establishment of home health services for the provision of services only to persons participating in the Energy Employees Occupational Illness Compensation Program (EEOICPA). Patients served under EEOICPA will not be considered when projecting need and the inventory of patients expected to be served will not be adjusted to reflect CON approvals for services under this program. Also, a new heading "Summary of Need Criteria" was added to clarify where the definitions section ended.
- aa. Page 26, new review criterion was added as item 4 to allow an application for the sole purpose of providing in-home nursing care to individuals eligible for benefits under the EEOICPA to be consistent with the State Health Plan.
- ab. Page 27, Hospice Service, the need calculation was revised to clarify all admissions are "unduplicated" counts.
- ac. Page 32, Diagnostic and Therapeutic Equipment and Procedures was revised to include language in the definition of "Cardiac Catheterization" to clarify how the Administrative Claims Data is used to determine utilization of services.
- ad. Page 32, the definition of "Diagnostic" was revised to remove language that stated cardiac permanent pacemaker/ICD device would be counted as a diagnostic catheterization.

- ae. Page 33, item c.i was revised to clarify that the most recently published *Administrative Claims Data Report*, would be utilized for the adult diagnostic cardiac catheterization rate.
- af. Page 43, Megavoltage Radiation Equipment, item 1.c was deleted and item 2 was revised to remove language that referred to the deleted subsection.
- ag. Page 48, Miscellaneous Services, Ambulance Service was revised to include class VI ground ambulances as requiring a CON under the State Health Plan and to explain the services provided by Class VI ambulance providers.
- ah. Page 49, Ambulatory Surgical Center was revised to clarify that pain procedures performed in a procedure room and cycstopy rooms as reported in the *Kentucky Annual Ambulatory Surgical Services Report* and the *Kentucky Annual Hospital Utilization and Services Report* are not included in the need calculations.
- ai. Page 53, Private Duty Nursing Services, new items 3 and 4 were added to state new criteria to be met when an applicant is proposing to establish private duty nursing services for the provision of services to pediatric patients (under age 18) or for the provision of Model II Waiver services to Medicaid recipients.
- aj. Page 54, Attachment A referenced on page 9 was added to the document.

The total number of pages incorporated by reference in the administrative regulation is seventy-four (74).